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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,768	01/14/2004	Peter J. Littrup	040090-000110US	5489

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EXAMINER	
VRETTAKOS, PETER J	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/757,768	LITTRUP ET AL.	
	Examiner	Art Unit	
	Peter J. Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *1-19 and 29-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/14/05; 1/31/05.* 6/24/04 PV
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to a gas-based cryoprobe, classified in class 606, subclass 20.

II. Claims 14-19, drawn to a liquid based cryoprobe, classified in class 606, subclass 20.

III. Claims 20-28, drawn to a method for cooling material, classified in class 128, subclass 898.

IV. Claims 29-34, drawn to a flow port, classified in class 604, subclass 30.

V. Claims 35-37, drawn to a method for temperature determination, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions I,II and III ,V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus or by hand such as cooling with a non-cryogenic cooling device.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Groups I-V is not required for Groups I-V, restriction for examination purposes as indicated is proper.

During a telephone conversation with Patrick Boucher on 8-14-05 a provisional election was made without traverse to prosecute the invention of Group III, claims 20-28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-19 and 29-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claimed method involves positioning a cryoprobe in a "material". Claims 24 and 25 claim the material as an imaging array and electronic circuits in a device, respectively. This is non-sensical because it reads that a cryoprobe is being inserted into an imaging array or electronic circuit for purposes of cooling those devices. The premise of the instant application is toward a cryoprobe for treating biological tissue, which is the "material" the Examiner has presumed in the rejections below. The specification provides no answers to these concerns.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baust et al. (5,520,682) in view of Armao (3,889,680) and further in view of Wright et al. (5,147,538) and even further in view of Bishop et al. (6,848,502).

Baust discloses a cryotherapy method with liquid nitrogen (col. 6:1-2) used as a cryogen in multiple cryoprobes (figure 1, col. 19:21-22, col. 7:47-49) in which the critical

point is estimated (col. 13:16-38) with an *implied* attempt to avoid "vapor lock" (as defined by a stoppage in a lumen caused by gas bubbles, which can arise with changes in pressure, temperature, or volume). This implication is found in col. 9:66 through col. 10:25. Further, cryoprobe dimensions and the use of multiple probes for organ or tumor treatment are provided in col. 7:30-51.

*Baust neglects to **expressly** disclose the phrase "vapor lock".*

Armao discloses an analogous cryotherapy method with a cryoprobe in which the term, "vapor lock" is disclosed as a phenomenon that is to be avoided (col. 8:1-5, figures 3 and 4) (because it would impede heat transfer). Armao's statements are wholly consistent with concerns posited by Baust in col. 9:66 through col. 10:25.

For further support of the argument that the prior art has made avoidance of vapor lock obvious two more relevant patents are presented. Wright discloses a pump (16) with a pump head **cooling assembly** (20) designed to avoid vapor lock (col. 5:33-35). Bishop discloses a method and apparatus for warming and storage of **cold fluids** in which numerous references are made to wanting to avoid vapor lock (col. 5:22-33, col. 16:64-67).

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Baust in view of Armao and further in view of Wright et al. and even further in view of Bishop et al. by including into the Baust cryotherapy method, the express statement that "vapor lock" is to be avoided. The motivation would be to provide an explicit caveat to avoid vapor lock, which could block the flow of cryogen in the cryoprobe.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baust et al. (5,520,682) in view of Armao (3,889,680) and further in view of Wright et al. (5,147,538) and even further in view of Bishop et al. (6,848,502) and even further in view of Dobak (5,275,595).

Only Dobak makes obvious 33.5 atm.

Dobak discloses a cryosurgical method with pressures that make obvious 33.5 atm. See patented claim 9. (33.5 atm is "less than 740 psi", *which is less than 51 atm*).

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Baust in view of Armao and further in view of Wright et al. and even further in view of Bishop et al. and even further in view of Dobak by including into the Baust cryotherapy method, 33.5 atm. The motivation would be to introduce to the Baust method as well-known/published pressure parameter.

Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baust et al. (5,520,682) in view of Armao (3,889,680) and further in view of Wright et al. (5,147,538) and even further in view of Bishop et al. (6,848,502) and even further in view of Gudkin et al. (4,519,389).

Only Gudkin discloses thermoelectric cryoprobes potentially used for electrical ablation.

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Baust in view of Armao and further in view of Wright et al. and even further in view of Bishop et al. and even further in view of Gudkin by including into the Baust cryotherapy method, electrical ablation. The motivation would be to increase the applicability of the Baust method.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baust et al. (5,520,682) in view of Armao (3,889,680) and further in view of Wright et al. (5,147,538) and even further in view of Bishop et al. (6,848,502) and even further in view of Stern et al. (5,741,248).

Only Stern discloses injections.

Stern discloses injecting cryosensitive agents use a cryoprobe with the needed structure in conjunction with cryosurgery (see Abstract).

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Baust et al. (5,520,682) in view of Armao (3,889,680) and further in view of Wright et al. (5,147,538) and even further in view of Bishop et al. (6,848,502) and even further in view of Stern et al. (5,741,248) by including into the Baust cryotherapy method, a cryoprobe capable of injection. The motivation is to increase the number of potential applications of the Baust system/method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Roy D. Gibson

Pete Vrettakos
August 19, 2005

ROY D. GIBSON
PRIMARY EXAMINER